

The Department of Health (DoH) says it is in the process of formulating a health technology (HT) strategy that will allow for the creation of a national unified HT system aimed at facilitating the safe and appropriate use of medical devices in both the private and public sectors. It is also considering the establishment of an essential equipment list or package similar to the state's essential drug list in a bid to prevent the indiscriminate introduction of technology that is not suitable to the country's disease profile.

This comes ahead of the establishment of the long-awaited SA Health Product Regulatory Authority (SAHPRA) that will replace the Medicines Control Council (MCC) and have oversight over the approval and registration of all health products including medicines and medical devices.

Speaking at last month's inaugural SA Medical Devices Industry Conference, the health department's deputy director-general: Ministerial Project Health Technology, Nonkonzo Molai, said while the establishment of the new regulatory authority is still at least a year away, it is imperative that government moves quickly to address the challenges that prevent equal access to safe, appropriate and cost-effective HT.

#### Equipment audit

The first step will be to conduct a national audit of all equipment in both sectors to establish what is available and how the distribution can be changed to allow improved access. Describing the current equipment infrastructure in the state sector as 'disjointed and chaotic', Molai said lack of control over the procurement of devices and the fragmentation of acquisition processes had resulted in a total mismatch between need and available technologies. Furthermore, at least 20-40% of expensive high-tech equipment bought by the state is standing idle because of a shortage of skills to operate them while poor maintenance practices have resulted in high replacement costs.

"We are procuring a lot instead of maintaining a lot," Molai noted, urging the devices industry to assist her department with the training of clinical engineers and the setting of standards of usage and maintenance of equipment.

#### Health Technology Assessment

Emphasising the need for evidence-based health technology assessment (HTA) mechanisms to ensure the appropriate introduction, safety and clinical efficacy of HT, Molai said the input of all stakeholders was needed to ensure the adoption of a relevant HTA model for SA.

Also speaking at the conference, the outgoing chairperson of the SA Medical Devices Industry Association (SAMEDI), Mike Howe-Ely, warned that full HTA evaluations as required for medicines registered in SA would not be feasible as it would be too time-consuming and prevent patient access to potential life-saving technologies.

The main objective of such assessments should be to provide patients timely access to the most promising innovative technologies while simultaneously providing a

stronger, locally relevant medical device-specific evidence base, Howe-Ely explained.

Reiterating SAMED's position that HTA should only be applied to new products entering the market, he said these evaluation should be done early in the life cycle of a new device and be subjected to regular review, particularly when new evidence become available. This would allow reimbursement soon after approval while also minimising the risk of wasting money on treatments that offer little value to patients.

"To support timely access to technologies that have limited but promising evidence of major potential impact but do not meet current evidentiary standards when launched, alternative funding mechanisms may be explored, such as 'conditional reimbursement' or 'coverage with evidence development'", Howe-Ely said.

He urged government to involve both industry experts and healthcare professionals in the designing of an appropriate HTA process that is 'transparent, clear and time-defined'.